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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

Purpose: We evaluated preferences for current urinary and sexual function following radical prostatectomy in men with clinically localized prostate cancer. We used utility assessment to quantify patient preferences.

Methods: We measured preferences in 209 community volunteers enrolled in a prostate cancer screening study who had radical prostatectomies between 1994 and 1998. We compared preferences for three outcome groups: (1) men who were bothered by both their current urinary and sexual functioning, (2) men who were only bothered by their current sexual functioning, and (3) men who were not bothered by either. Preferences were assessed via computer-based interview using time trade-off and standard gamble methods. Functioning was assessed via standardized questionnaire.

Results: Differences in utilities were found by outcome group, with median utilities high across groups (0.9 for TTO and Standard Gamble), indicating that men were not willing to give up much remaining life years (1 year or 10% risk of death) with current functioning to achieve ideal functioning.

Conclusion: Health related quality of life is generally good in patients treated for prostate cancer with radical prostatectomy; and those who have urinary and/or sexual dysfunction would not be willing to trade much of their remaining life span to have perfect functioning.

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Introduction

This project provides a novel opportunity to measure preferences for key health outcomes in a well-characterized cohort of men with prostate cancer detected via prostate-specific antigen (PSA) and treated with radical prostatectomy between 1994 and 1998. This project is innovative in that no previous investigators have assessed preferences for outcomes in a large cohort of men who were actually experiencing the post-treatment outcomes of interest. Because we had recently evaluated urinary and sexual function and bother in this cohort,[1] we were able to stratify our cohort to target men for further study that had experienced a range of outcomes in these domains. More specifically, we systematically measured preferences for living with a health state in men who were experiencing problems with urinary and/or sexual functioning and men who were not experiencing problems in these domains. Final analysis indicates significant differences in preferences by outcome group. Ultimately, linking preferences for health states with current functioning will provide more accurate estimates of patient preferences for use in decision analysis models. These models are of critical importance because the proportion of men in the US being screened and treated for prostate cancer is increasing.[2] Although direct evidence from randomized controlled trials are likely to provide the most definitive estimate about the overall effectiveness of screening and treatment for prostate cancer, the results of such studies will not be available for many years. Decision makers- patients, physicians, and health policy makers – must act before these results are available. Supporting these decision makers requires a better understanding of how men feel about their quality of life after surgical management of their disease. These data will allow a more accurate evaluation of the immediate costs of screening in the absence of long-term data from randomized trials. Since the established risk factors for prostate cancer are largely non-modifiable, screening is the only currently viable method for affecting prostate cancer morbidity and mortality; therefore, we need to know how screening and resultant treatment affect quality of life.

Body

The following outlines the progress made during the funding period October 1, 1998 to March 31, 2001with regard to each task outlined in our originally-submitted "Statement of Work."

Task 1 "Development of computer-based health utility assessment module (months 1-6)"

Measures of health utilities are used to adjust estimates of life expectancy that are the endpoints of decision analysis models. Recently, interview and computer-based methods have been developed to measure health utilities in individual patients. These methods use techniques such as the standard gamble[3] or time trade off[4] to elicit utilities. Using these methods, preferences are derived implicitly based on the individual's response to decision situations.[5] For example, in the time trade-off method, an individual is presented with a paired comparison in which he or she must choose between two alternatives. In the case of a chronic health condition (i.e., incontinence following surgical treatment for prostate cancer), one alternative is to live with the chronic condition for the remainder of life, the second alternative is to have a shorter life, but to live in the absence of the chronic condition. The individual is asked to choose between theses two alternatives, varying the length of the "shorter life" until the individual is indifferent between the two alternatives. The indifference point is the utility for the chronic condition. The less desirable the health condition, the greater the amount of life the individual will give up in order to be free of the chronic condition. In this instance, the chronic condition would have a low utility.

For the current project we have used the U-titer computer program[6] as the platform for building automated preference interviews. More specifically, we have successfully computerized both standard gamble and time trade-off methods for eliciting utilities for current health states in our patient groups. The final version of the interview was completed after testing preliminary programs with 25 pilot subjects (men with prostate cancer who were not eligible for the current study). To use the automated interview, the subject sits in front of the computer and answers a series of questions presented on the screen. The subject responds to questions using a track ball to select the appropriate answers. Overall, the computerized interview was well accepted by our subject population. The majority of subjects were able to complete the interview independently after a brief introduction by the research assistant. More specifically, only 11 of 237 (5%) interviews had to be excluded from the final analysis due to misordering of practice utilities indicating that the subject did not understand the format of the interview.

The second task completed in the initial 6 months was the development of databases and quality control procedures for data management. More specifically, databases were created to link the computerized interview data with the questionnaire responses measuring current urinary and sexual functioning.

Tasks 2 & 3 "Participant selection and data collection (months 7-24)"
"Statistical Analysis and write-up of results (months 25-30)."

Participants were recruited from our ongoing longitudinal study of outcomes in men with screen-detected prostate cancer (N=2,237).[7] Because these men were all originally enrolled in our PSA screening studies, we had extensive data regarding demographics, primary treatment, and cancer stage and grade. In addition, we also had extensive information regarding quality-of-life outcomes after treatment.[1] As per our original grant proposal, we selected for further study only those men who had cancer detected between 1994 and 1997, had radical prostatectomy as their primary treatment, and had returned a prior questionnaire measuring quality of life (N=432). We selected this time frame so that outcomes would be more likely attributed to the treatment and not to aging per se; we selected only surgery patients because this treatment is being increasingly used in the US. Additionally, within this cohort of 432 men we defined *a priori* positive, intermediate, and negative health states based on previous self-reports of urinary and sexual functioning. We defined these health states based on prior responses to questions regarding the level of bother associated with current urinary function and level of bother associated with current sexual function. More specifically, we selected for further study men from three categories of outcomes: (1) men who were bothered by both their current sexual and urinary functioning, (2) men who were bothered by their current sexual functioning, but not urinary functioning, and (3) men who were not bothered by either their current sexual or urinary functioning. By sampling men from these outcome categories, we hoped to obtain utilities from equal number of men within each of these health states; however, we also reassessed their current urinary and sexual functioning to monitor potential drift between outcome categories.

To serve as our sampling frame, we randomly selected approximately 80 men from each of the three outcome categories defined above. Within these groups, we again randomly selected men until we had recruited ~50 men in each group who had completed the interview and the reassessment of function and bother. Refusal rates ranged from 12-16% across groups. Of the men who agreed to participate, we also randomly selected a subset of 30 men to complete the computerized interview twice at two-week intervals to assess test-retest reliability of the computerized interview. We found an interclass correlation coefficient (ICC) of 0.8 for the time trade-off method and an ICC of 0.7 for the standard gamble method of assessment of utilities. These values were within the range of other computerized assessments of utilities[8] and indicated that the computerized measures had acceptable test-retest reliability.

Of the 155 who completed the interview and the questionnaire, approximately 40% drifted from their original outcome group when recategorized based on current urinary and sexual function. This was especially problematic for the group originally bothered by both urinary and sexual function. More specifically, based on the questionnaire responses at the time of the utilities assessment, 58% of these men drifted from their original group to either (1) having only bother associated with sexual function, or (2) not bothered by either sexual or urinary function. In the other two original study groups, only 30% of the men were recategorized based on current functioning. Overall, the utility for current health state was high when measured via either standard gamble or time trade-off (mean $\pm$ sd = .90 $\pm$ .25 and .86 $\pm$ .27, respectively). An analysis including all the completed interviews showed a significant difference in mean utilities assessed via standard gamble method when comparing the original groups (see Appendices, Table 1). Significant group differences for both the time trade-off and standard gamble utilities were also found when outcome groups were recategorized based upon most recent functioning (see Appendices, Table 2). Therefore, these preliminary results indicated that men with greater bother associated with sexual and urinary functioning were willing to give up more life to be in perfect health. These results support our original hypothesis. However, we were concerned that the sample size for the recategorized group for bother associated with both sexual and urinary function was too small (N = 26) to provide stable estimates of the mean utilities. Therefore we gained approval from the DOD to recruit additional men to increase the number of subjects in the group including men bothered by both sexual and urinary functioning (i.e., to increase the sample size to ~50 as proposed originally). We used the same eligibility criteria for recruiting new participants, except to extend the cutoff for treatment from 1997 through

1998. This change in the study criteria provided 82 additional participants (final N = 237). However, of the 237 men, 28 were excluded due to utility misorders (N=11), urinary dysfunction only (N=10), or the final outcome group could not be determined due to incomplete questionnaire (N=7). As shown in Table 3, significant group differences in both time trade-off and standard gamble utilities were also found with the expanded study sample, indicating that men with worse outcomes were willing to trade off more remaining life years to be in perfect health.

In addition to completion of data analysis, we have also finished a preliminary manuscript that describes the study methods and reports the study results in detail. We anticipate submitting this manuscript for peer review in the next month. A copy of this manuscript is included in the appendices.

Key Research Accomplishments

(1) Development of computerized interview for assessment of preferences for health states in men with prostate cancer.

(2) Achieved acceptable test-retest reliability for computerized interview.

(3) Achieved original and amended participant recruitment goals.

(4) Performed final data analysis showing significant differences in outcome groups with regard to preferences for current health states. These results supported our original hypothesis that men with worse disease-specific health states with regard to urinary and sexual functioning would report significantly lower utilities for their health states then men who were living with more positive outcomes.

(5) Completed preliminary manuscript detailing methods and results of the study.

Reportable Outcomes

(1) Development of a reliable computerized interview for assessment of preferences for health states in men with prostate cancer.

(2) Development of a database with preferences for health states linked to objective measures of quality of life and clinical data.

(3) Mean utilities for quality-of-life outcomes after surgical management of prostate cancer were high (< .85), indicating that men were not willing to trade-off many remaining life years in the current state of health in order to be in perfect health. However, we did find differences in utility measures that corresponded with objective measures of functioning. More specifically, men bothered by their urinary and sexual functioning were more willing to trade-off time in the current state of health compared with men less bothered by their current functioning.

Conclusions

The results of this study indicated significantly lower utilities for men bothered by both their current sexual and urinary functioning. However, the overall mean utilities were high (ranging form .86 to .90), indicating that men who have undergone surgical management of prostate cancer are not willing to trade-off much to be in perfect health. This indicates that the quantification of quality-of-life outcomes may need to be reevaluated in decision analysis models. Measurement of patient preferences for health states following prostate surgery has never been performed in a large sample of men who were actually experiencing the outcomes of interest. In addition, the current study provides a link between utilities for health following surgical management of prostate cancer and more widely used measure of functional status and bother. Such a linkage will be of increased importance as outcomes studies employing these measures are used as the basis for decision analysis and cost-effectiveness analysis.

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Appendices

Table 1

Mean and Median Time-Trade Off and Standard Gamble Utilities, Stratified by Original Outcome Group (Original Sample N = 155)

Outcome Group:	Bothered by Urinary and Sexual Functioning (N =55)	Bothered by Sexual Functioning (N=50)	Bothered by Neither (N=50)	P*
Time-Trade Off Method				
Mean (±SD)	.81 (±.31)	.90 (± .20)	.88(± .28)	0.3
Median	.92	94	.99	
Standard Gamble Method				
Mean (±SD)	.83 (± .31)	.96 (± .11)	.93 (± .26)	.002
Median	.94	.99	.99	

* = P values represent results for Kruskal-Wallis test.

Table 2

Mean and Median Time-Trade Off and Standard Gamble Utilities, Stratified by Recategorized* Outcome Groups (Original Sample N = 155)

Outcome Group:	Bothered by Urinary and Sexual Functioning (N =26)	Bothered by Sexual Functioning (N=62)	Bothered by Neither (N=57)	P**
Time-Trade Off Method				
Mean (±SD)	.74 (±.31)	.85 (± .24)	.92 (± .25)	0.001
Median	.82	.92	.99	
Standard Gamble Method				
Mean (±SD)	.79 (± .35)	.89 (± .25)	.96 (± .21)	0.0001
Median	.91	.99	.99	

* = Outcome groups were recategorized based on reassessment of bother associated with sexual and urinary function at the time of the computerized interview. Ten (10) men were excluded from the analysis because their original outcome group shifted from "bothered by both urinary and sexual function", or "bothered by sexual function only", to "bothered by urinary function only." The latter outcome group was not included in our original study in that proportionately very few men were bothered only by urinary functioning.

** = P values represent results for Kruskal-Wallis test.

Table 3

Mean and Median Time-Trade Off and Standard Gamble Utilities, Stratified by Recategorized* Outcome Groups (Final Sample N = 209)

Outcome Group:	Bothered by Urinary and Sexual Functioning (N =40)	Bothered by Sexual Functioning (N=95)	Bothered by Neither (N=74)	P**
Time-Trade Off Method				
Mean (±SD)	.77 (±.31)	.87 (± .29)	.92 (± .21)	0.0007
Median	.88	.95	1.0	
Standard Gamble Method				
Mean (±SD)	.82 (± .27)	.90 (± .20)	.96 (± .17)	0.0001
Median	.94	.99	1.0	

* = Outcome groups were recategorized based on reassessment of bother associated with sexual and urinary function at the time of the computerized interview. Ten (10) men were excluded from the analysis because their original outcome group shifted from "bothered by both urinary and sexual function", or "bothered by sexual function only", to "bothered by urinary function only." The latter outcome group was not included in our original study in that proportionately very few men were bothered only by urinary functioning. An additional 11 men were excluded due to utility disorders, and 7 men were excluded because the final outcome group could not be determined due to an incomplete questionnaire

** = P values represent results for Kruskal-Wallis test.

PATIENT PREFERENCES FOR OUTCOMES ASSOCIATED WITH SURGICAL MANAGEMENT OF PROSTATE CANCER

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ABSTRACT

Purpose: We evaluated preferences for current urinary and sexual function following radical prostatectomy in men with clinically localized prostate cancer. We used utility assessment to quantify patient preferences.

Materials and Methods: We measured preferences in 209 community volunteers enrolled in a prostate cancer screening study who had radical prostatectomies following discovery of localized prostate cancer between 1994 and 1998. We compared preferences for three outcome groups: (1) men who were bothered by both their current urinary and sexual functioning, (2) men who were only bothered by their current sexual functioning, and (3) men who were not bothered by either their current sexual or urinary functioning. Preferences were assessed via computer-based interview using both time trade-off and standard gamble methods. Current functioning was assessed via standardized questionnaire. Preferences were compared across groups, controlling for clinical characteristics and demographic factors.

Results: Median utilities were high across outcome groups (0.9 for TTO and Standard Gamble), indicating that men were not willing to give up much remaining life years (1 year or 10% risk of death) with current functioning to achieve ideal functioning. Specifically, TTO and SG mean scores increased as burden decreased (.767 and .822 for both sexual and urinary dysfunction; .869 and .898 for sexual dysfunction only; .923 and .956 for no dysfunction).

Conclusion: Health related quality of life is generally good in patients treated for prostate cancer with radical prostatectomy; and those who have urinary and/or sexual

dysfunction would not be willing to trade much of their remaining life span to have perfect functioning. Radical prostatectomy side effects did not diminish quality of life to a clinically important extent in this observational study of surviving volunteer subjects.

INTRODUCTION

Among U.S. men, prostate cancer is the most common non-skin cancer and the second leading cause of male cancer deaths.[1] Moreover, age-adjusted incidence rates and mortality rates have increased dramatically in recent years.[2] Because the only well-established risk factors are age, African-American race, and positive family history, efforts directed toward primary prevention are not currently feasible.[3] Therefore, secondary prevention, which includes both screening and early detection, has assumed heightened importance and controversy.[4]

Currently, the two best methods for early detection of prostate cancer are digital rectal examination (DRE) and measurement of serum prostate-specific antigen (PSA) concentration.[5,6] Although a recent population-based study has shown changes consistent with stage migration from advanced to localized prostate cancer with the advent of increased PSA screening,[7] there is no direct evidence from randomized controlled trials that screening reduces disease-specific mortality rates. This lack of evidence, coupled with concerns about the negative effects of treatment on quality of life, has led to disagreement about the net benefits of screening. Currently, the American Cancer Society and the American Urological Association recommend offering annual screening for men aged 50 years and older with both DRE and PSA. In contrast, the U.S. Preventive Services Task Force does not recommend screening with either test.[8]

Health-related quality of life refers to the physical, emotional, and social domains of health, which can be influenced by a person's experiences, beliefs, expectations, and perceptions.[9] Most published reports of health-related quality of life in men with prostate

cancer have focused on those with metastatic disease.[10,11] However, based on findings from large screening studies, most men with prostate cancer detected through PSA screening have clinically localized disease (i.e., 97%), and approximately 70% of these men who opt for radical prostatectomy also have pathologically organ-confined disease.[12] It is possible that different aspects of health-related quality of life may be more salient for men with localized disease as compared with those with advanced disease. For example, men with localized disease may be more concerned about treatment-related decrements in sexual function than men with advanced disease. Consequently, quality-of-life measures should be sensitive to the concerns of men at all levels of disease status. Furthermore, from a population health perspective, we know little about the effects of treatment on quality of life among men with clinically localized disease.

A cross-sectional investigation in men with localized prostate cancer found decrements in disease-specific health-related quality of life, but no decrement in general health-related quality of life compared to men without prostate cancer.[13] These investigators concluded that both general and disease-specific measures should be used to assess outcomes in men treated for localized prostate cancer. The use of psychometrically-sound and valid measures will allow standardized comparison of outcomes in disparate patient populations.

In addition to patient self-reports of changes in health-related quality of life (such as described above), it is also important to quantify patient preferences for outcomes (including outcomes such as changes in quality of life) that may result from medical interventions.[14] Therefore, not only are the outcomes themselves measured, but the *desirability* (or undesirability) of the outcome is also measured. The strength of a

patient's preference for an outcome is also referred to as the patient's "utility" for a specific health outcome.[14]

In attempting to quantify preferences for outcomes, investigators relied primarily on expert panels of clinicians, rather than actual patients, to assign utilities for various outcomes such as incontinence, impotence, and progression to metastatic disease. If the goal of screening and treatment is to improve health outcomes that matter to patients, their preferences should be incorporated into the analysis. The need to assess the preferences of patients is highlighted by the fact that patients and physicians may feel quite differently about health outcomes. For example, as part of a randomized trial of orchiectomy alone *versus* goserelin plus flutamide in men with metastatic prostate cancer, researchers found a marked discrepancy between physicians's evaluations and patient's opinions with regard to subjective morbidity associated with treatment.[11]

Standardized assessment of diverse patients' preferences for a range of outcomes may inform screening and treatment decisions. More specifically, future research should focus not only on the health states that may result from screening, but also how individuals perceive these outcomes.

We used existing instruments to measure both general and disease-specific health-related quality of life domains in men treated with radical prostatectomy. We tested the following hypothesis:

Men experiencing worse disease-specific health states with regard to urinary and sexual functioning will report at least a 10% lower utility for their health states then men who are living with more positive outcomes. This indicates willingness to surrender 10% more of remaining life to be in ideal health compared to the current health state.

MATERIALS AND METHODS

Study Participants.

Participants were recruited from our ongoing longitudinal study of outcomes in men with screen-detected prostate cancer (N = 2,237). Because these men were all originally enrolled in our PSA screening studies, we have extensive data regarding their pre-diagnosis PSA values, treatments, and cancer stage and grade. We also collect demographic data and have extensive information regarding quality-of-life outcomes post-treatment. The preliminary quality-of-life outcomes for men with cancer detected between 1989 and 1995 have been reported elsewhere.[15]

Patient selection included men who had cancer detected between 1994 and 1998, had radical prostatectomy as their primary treatment, and returned the quality-of-life questionnaire (n = 594). We selected this time frame so that outcomes would be more likely attributed to the treatment and not to aging per se; we selected only surgery patients because this treatment is widely used in the US. Additionally, within this cohort of 594 men we defined *a priori* positive, intermediate, and negative health states based on previous self-reports of urinary and sexual functioning. We defined these health states based on prior responses to questions regarding the level of bother associated with current urinary function and level of bother associated with current sexual function. More specifically, we selected for further study men from three categories of outcomes: (1) men who are bothered by both their current urinary and sexual functioning, (2) men who are bothered by their current sexual functioning, but not urinary functioning, and (3) men who are not bothered by either their current sexual or urinary functioning. Very few men (8 patients) were bothered by their urinary function without also being bothered by

their sexual function. Therefore, utilities for this pattern of outcomes were not evaluated. By randomly sampling approximately 100 men from these outcome categories (N=387), we hoped to obtain completed utilities for at least 50 men within each of these health states; however, we reassessed their current urinary and sexual bother so that potential drift from one outcome category to another could be evaluated. The 387 men identified as potential participants were mailed a cover letter asking if they would be interested in participating in a computer-based measure of patient preferences, and quality of life questionnaire similar to the one they completed in the past. Those who agreed to participate completed the study instruments as described below. Informed consent was obtained from all study participants.

Study Instruments.

The study instruments consisted of the quality-of-life self-administered questionnaire and computer-based measures of patient preferences for current health.

Quality-of-life questionnaire. Items from the self-administered questionnaire include: (a) the RAND 36-Item Health Survey 1.0 (a global quality of life measure that assesses current physical function, physical health, and emotional well-being);[16] (b) current urinary and sexual function and bother scales (developed and validated in men with clinically localized prostate cancer by researchers at UCLA);[13] and (c) current medical conditions. Both the RAND 36-Item Health Survey and the disease-specific measures have demonstrated acceptable test-retest reliability and internal consistency.[13,16]

Computer-based measures of patient preferences. Measures of health utilities (i.e,. patient preferences for specific health outcomes) are used to adjust estimates of life expectancy that are the endpoints of decision analysis models. Interview and computer-based methods have been developed to measure health utilities in individual patients, using techniques such as the standard reference gamble[17] or time trade-off[18] to elicit utilities. Using these methods, preferences are derived implicitly based on the individual's response to decision situations.[14] For example, in the time trade-off method (TTO), an individual is presented with a paired comparison in which he must choose between two alternatives (Figure 1). In the case of a chronic health condition (i.e., incontinence following surgical treatment for prostate cancer), one alternative is to live with the chronic condition for the remainder of his life, the second alternative is to have a shorter life, but to live in the absence of the chronic condition. The individual is asked to choose between these two alternatives, varying the length of the "shorter life" until the individual is indifferent between the two alternatives. The ratio of life expectancy at the indifference point and the life expectancy with the chronic condition is the utility for the chronic condition on a clinical utility scale from 0 to 1. The situation is similar for the standard gamble (SG) technique (Figure 2). The individual is asked if he would be willing to take a "magic pill" that results in either cure or sudden death with varying probability, versus living in his current state of health. The less desirable the health condition, the greater the risk of death the individual will tolerate in order to be free of it.

Our assessment employed U-Titer, a platform for building automated preference interviews.[19,20] The interviews were self-administered via computer after a brief introduction and practice session overseen by a research assistant. The practice session

asked participants to provide utilities for monocular blindness versus binocular blindness. Eleven (11) participants who "misordered" these utilities (i.e., binocular blindness was given a higher utility compared with monocular blindness) were excluded from the analysis due to concern regarding their understanding of the task.

All participants completed the computer-based measure first and then the quality of life questionnaire, so as not to bias the responses to the computer-based measure. Final outcome groups (both urinary and sexual dysfunction, sexual dysfunction only, or neither urinary or sexual dysfunction) were determined based on the responses to the quality-of-life questionnaire obtained at the time of the computerized interview.

Data Analysis.

Basic demographics and clinical data were compared between those recruited and not recruited for the study. We also compared the demographic and clinical data for men who refused or were deceased compared with those who participated, and those excluded (misorders, those with urinary dysfunction only, and those whose outcome group could not be determined) versus those included in the final sample. Demographic and clinical data were also compared between final outcome groups. T-tests or chi-square tests were used for each of the aforementioned comparisons. Kruskal-Wallis test was used for comparison of utilities among the three outcome groups. Wilcoxon post-hoc comparisons were used for pairwise comparisons of utilities by outcome group. We also compared utilities by number of comorbid medical conditions, race, and age.

Power

The study was powered to detect a difference of at least 0.1 in utilities between groups of men with different post-treatment health outcomes. This difference translates into being willing to give up 10% more of remaining life to be in ideal health compared to the current health state. To put such a difference in context, among patients with visual impairment, previous studies have found that the average difference in utilities for monocular and binocular blindness was 0.36,[21] the difference between utility for mild angina symptoms and severe angina symptoms was 0.22,[22] and a gain in utility for vision from cataract extraction of 0.07.[23] With a sample size of approximately 50 men in each study group (á = .05 with 2-tailed tests), power was $\geq$ 80% to detect a difference of 0.1 scale points between the men who are bothered by both their urinary and sexual function *versus* men who are not bothered by either their urinary or sexual function.

RESULTS

Comparison of Demographic and Clinical Data for Study Participants versus Non-Participants

Among the total sample of 594 patients, 387 were randomly selected for recruitment into the study, while it was not necessary to recruit the remaining 207 in order to meet our sample goals (see Table 1). Chi-square analyses revealed no significant difference by recruitment status for marital status, education, employment, income, number of comorbidites, smoking history, preoperative PSA, cancer stage, or Gleason grade (Table 1). Similarly, there were no differences between groups with regard to the participants' age at the time of the questionnaire ($p=.5$). However, a t-test revealed a statistically significant, but not clinically significant difference in the interval between the date the recruitment letter was sent and the surgical date ($p=.02$) (mean months: 34.1 not recruited vs. 35.7 recruited). Trend analyses ($p<0.1$) showed a difference between race ($p=0.09$) and place of surgery ($p=.060$), with African-Americans more likely recruited and men who underwent surgery at Washington University more likely recruited (Table 1).

Among the sample recruited (n=387), we also compared clinical and demographic variables between those who participated (n=237) and those who refused or were deceased (n=150) [see Table 1]. There was a statistically significant difference with respect to race ($p=.03$), with Whites more likely to refuse or to be deceased at the time of recruitment (Table 1). Trend analyses showed a difference between interval between the surgical date and recruitment letter ($p=.09$), and pre-operative PSA ($p=.09$), with men with pre-operative PSA ≥ 4 ng/mL more likely to participate in the study (Table 1).

Among the sample excluded from the final analyses (outcome group could not be determined, n=7; urinary dysfunction only, n=10; and utility misorder, n=11), versus those who remained in the analyses (n=209), there was a statistically significant difference with respect to marital status (p=.014), with those currently married more likely to be included, smoking status (p=.05), with nonsmokers more likely included,and place of surgery (p=.005), with those who underwent surgery at Washington University more likely included in the final analysis. Trend analysis showed a difference between interval from surgery to mailing (p=.08), and race (p=.06), with Whites more likely included compared with African-Americans.

Comparison of Demographics and Clinical Data by Outcome Group

Demographic and clinical data stratified by outcome group are shown in Table 2. Statistically significant differences were found for number of comorbidities (p=.01) and pre-operative PSA level (p=.03). More specifically, men with ≥ 2 comorbid medical problems were more likely to report both sexual and urinary dysfunction. Surprisingly, men with pre-operative PSA ≥ 4.0 ng/mL were more likely to report neither urinary or sexual dysfunction.

Outcome group by Utility

Table 3 shows there is a statistically significant difference between utility score by outcome groups for both the time trade off method (p=.0007) and standard gamble method (p<.0001), where utility scores decrease with increased level of dysfunction. Similar analyses showed no significant difference with respect to race and comorbidities.

Wilcoxon pairwise post-hoc comparisons showed significant differences between the TTO utility scores of .87 for sexual dysfunction only versus .92 for neither

dysfunction (p=.0002), and SG scores of .89 and .96 for corresponding dysfunction groups (p<.0001), demonstrating that sexual dysfunction post radical prostatectomy would result in patients being willing to give up a significantly larger amount of time to be in perfect health compared with those with no dysfunction (approximately 5 to 6 years). Utility scores for both sexual and urinary dysfunction (.77) versus neither dysfunction (.92) for TTO (p=.015) and corresponding groups for SG (utility scores of .82 and .96 respectively, p<.0001) demonstrated that having both sexual and urinary dysfunction versus no dysfunction was worth giving up approximately 14 to 15 years difference, on average. Pairwise comparisons also found a statistically significant difference between the urinary and sexual dysfunction group and sexual dysfunction only group (p=.05) for SG, but not TTO, with a significant tradeoff of approximately 8 years between these two groups.

DISCUSSION

While it is commonly known that radical prostatectomy can cause adverse outcomes such as urinary and sexual dysfunction, it is challenging for physicians to help patients through this decision making process. Quantifying these outcome burdens with measures like the TTO and SG may help in very formal decision support processes. These methods examine the amount of life, or the risk of death, a patient would be willing to trade to be free of infirmity. Measurement of patient preferences for health following prostate surgery has never been performed in a large sample of men who are actually experiencing the outcomes of interest. In addition, the present study provides a link between utilities for health following surgical management of prostate cancer and

more widely used measures of functional status and bother. Such a linkage will be of increased importance as outcomes studies employing these measures are used as the basis for decision analysis and cost-effectiveness analyses. These models are of critical importance because the proportion of men in the US being screened and treated for prostate cancer is increasing.[7,24]

We found that post-radical prostatectomy sexual and urinary dysfunction results in a varying degree of burden felt by the patient (utilities ranged from .77 to .96). However, we also found that as level of dysfunction increased, so did the impact to the patient. Furthermore, there is little discrepancy of the burden carried by the patient between having both urinary and sexual dysfunction (.77 TTO and .82 SG), and having only sexual dysfunction (.87 TTO and .89 SG). However, we found that burden as assessed by utility assessment was independent of race and comorbid medical conditions, therefore warrenting pre-surgical counseling of the patient by the physician.

Utilities among prostate cancer surgery patients are validating of a patient's choice of aggressive treatment in comparison to the burden carried by treatment of other diseases. This can be illustrated by the comparison of the worst outcome of a prostatectomy (both sexual and urinary dysfunction) as having 8% (means .74 for SG vs. our .82) less burden on the patient as a removal of colorectal carcinoma among stage I rectal or stage I/II colon cancer patients.[25]

Study Limitations.

Although participants were chosen randomly from a priori outcome groups, our study sample included a higher proportion of African-American men and men with

surgeries at Washington University. The inclusion of a higher proportion of men with surgeries at Washington University may have resulted in higher mean utilities due to Washington University being a center of excellence for prostate cancer surgery and participant allegiance to treatment location. It is unclear if the inclusion of a greater proportion of African-American men biased the results. Since African-American men are more likely to have higher stage and grade cancers at the time of cancer detection it is possible that the results may have been biased in the direction of lower mean utilities.

Our study is limited in that we have only evaluated utilities in men who have continued to cooperate in our research program; therefore, we may be missing those who are unhappy with their outcomes. Additionally, since our cohort includes only those men who actively sought screening for prostate cancer, assessment of health utilities in our cohort may result in preferences for outcomes different from those found in men who did not proactively seek cancer screening. Finally, since our study is a cross-sectional design, we cannot assess whether utilities will change over time.

Assessing the validity of any utility assessment instrument is hampered by the absence of a gold standard. Several findings, however, suggest that U-Titer based instruments are a valid means for assessing utilities. First, instruments developed with U-Titer have been used successfully in approximately 4,000 interviews with more than 1,700 subjects, including a multi-center, multi-national randomized trial.[26] Second, the rate at which the interview grossly fails is low. We have determined the rate at which such failures occur with U-Titer-based instruments by comparing the utility of monocular blindness with that of binocular blindness. Because people should prefer to be blind in one eye rather than both eyes, interviews in which the utility for monocular blindness is

less than the utility for binocular blindness are likely to be interview failures. For studies in which utilities for both monocular and binocular blindness were assessed, the failure rate has ranged from less than 4% to about 8%. The typical failure rate is about 5%. Third, test-retest reliability of utilities assessed using U-Titer is good. Reliability tends to be better when assessing health states that the subject has experienced or are easily imagined, but the test-retest reliability for unfamiliar health states is generally adequate. Intraclass correlation coefficients over approximately two weeks range from about 0.50 to 0.80.[27,28,29,30,31] Fourth, utilities assessed with U-Titer correlate modestly with measures of symptom severity and bother, disease-specific health status and overall health status.[27,32,33,34,35] That is, people with reduced health status tend to have lower utilities than do people with better health status. Similarly, people who are more bothered by a specific health state tend to assign lower utilities than do those who are less bothered by the same health state. Finally, utilities assessed using U-Titer appear to be responsive to clinically relevant changes in quality of life. For example, cataract extraction appears to increase utilities by about 0.08; utilities increase by a similar amount in patients who receive hearing aids.[36]

CONCLUSIONS

Rational decision making in the setting of prostate cancer detection and treatment requires comparing the potential benefits of screening with the potential harms. Because utilities measure the gain in length of life needed to offset undesirable health state, they provide a formal method for characterizing that tradeoff. These results have important implications for patients contemplating aggressive treatment for prostate cancer.

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Figure 1. Example Utility Screen for Time Trade Off Measure

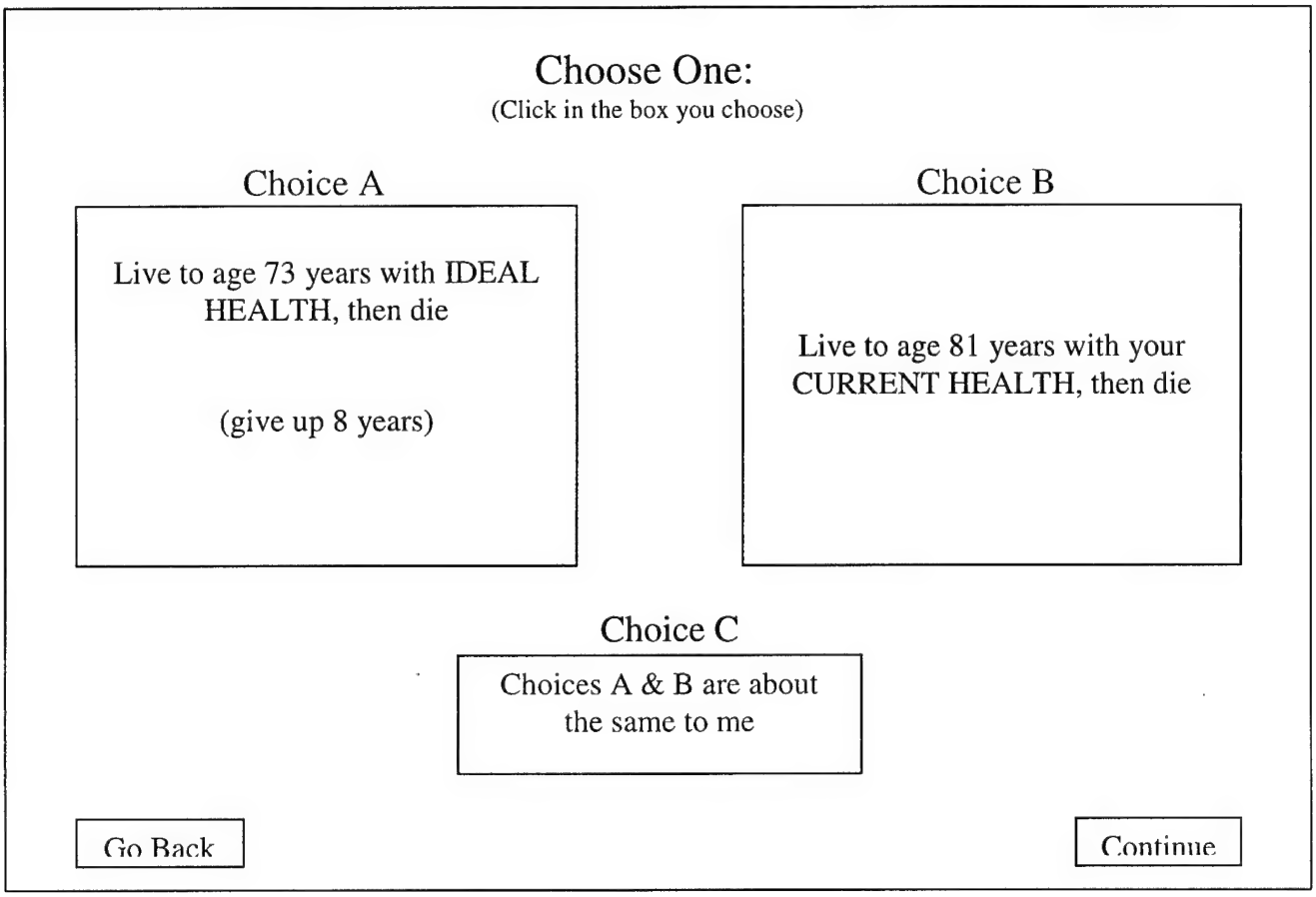

Figure 2. Example Utility Screen for Standard Gamble Measure

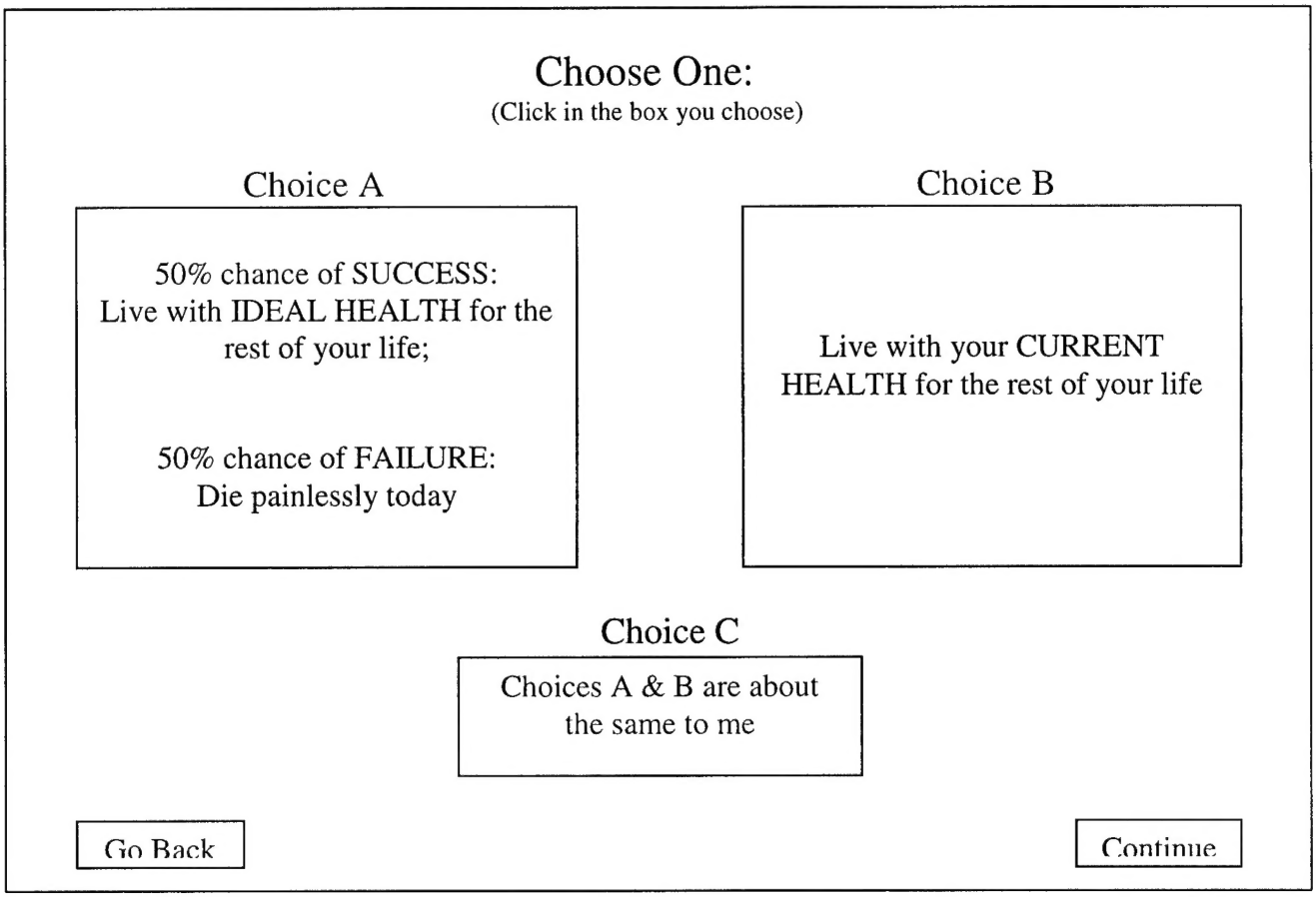

Table 1. Chi Square Analyses of Sample Selection of Eligible Radical Prostatectomy Patients

	N=594			N=387			N=237		
Numbers (percentages)*	Recruited N=387	Not Recruited N=207	P value	Participated N=237	Refused/ Deceased N=150	P value	Included N=209	Excluded N=28	P value
Race									
African American/Other	33 (76.7)	10 (23.3)	.098	26(78.8)	7(21.2)	.031	20(76.9)	6(23.1)	.059
White	354 (64.3)	197 (35.8)		211(59.6)	143(40.4)		189(89.6)	22(10.4)	
Marital Status									
Married	342(64.8)	186(35.2)		206(60.2)	136(39.8)		186(90.3)	20(9.7)	
Never Married	13(81.3)	3(18.8)	.395	8(61.5)	5(38.5)	.434	7(87.5)	1(12.5)	.014
Wid/Div/Sep	32(65.3)	17(34.7)		23(71.9)	9(28.1)		16(69.6)	7(30.4)	
Education									
<high school	13(54.2)	11(45.8)		7(53.9)	6(46.2)		6(85.7)	1(14.3)	
high school	94(69.1)	42(30.9)		53(56.4)	41(43.6)		45(84.9)	8(15.1)	
some college	99(64.7)	54(35.3)	.651	62(62.6)	37(37.4)	.654	57(91.9)	5(8.1)	.698
college	73(65.8)	38(34.2)		45(61.6)	28(38.4)		38(84.4)	7(15.6)	
postgrad	104(63.4)	60(36.6)		69(66.4)	35(33.7)		62(89.9)	7(10.1)	
Employment									
Retired	220(64.7)	120(35.3)	.798	140(63.6)	80(36.4)	.346	122(87.1)	18(12.9)	.569
Working	163(65.7)	85(34.3)		96(58.9)	67(41.1)		86(89.6)	10(10.4)	
Income									
<20,001	25(61.0)	16(39.0)		14(56)	11(44)		11(78.6)	3(21.4)	
20,001 to 30,000	51(66.2)	26(33.8)	.817	29(56.9)	22(43.1)	.667	26(89.7)	3(10.3)	.707
30,001 to 50,000	105(67.3)	51(32.7)		69(65.7)	36(34.3)		61(88.4)	8(11.6)	
>50,000	164(63.5)	94(36.4)		101(61.6)	63(38.4)		90(89.1)	11(10.9)	
Comorbidities									
0	202(65.2)	108(34.8)		118(58.4)	84(41.6)		107(90.7)	11(9.3)	
1	118(68.6)	54(31.4)	.305	76(64.4)	42(35.6)	.300	67(88.2)	9(11.8)	.222
2+	60(59.4)	41(40.6)		41(68.3)	19(31.7)		33(80.5)	8(19.5)	
Pre-opp PSA									
<4	170(66.9)	84(33.1)	.432	96(56.5)	74(43.5)	.088	82(85.4)	14(14.6)	.276
>=4	217(63.8)	123(36.2)		141(65.0)	76(35.0)		127(90.1)	14(9.9)	
Smoking Status									
Smoker	18(60)	12(40)	.540	14(77.8)	4(22.2)	.140	10(71.4)	4(28.6)	.048
Non-smoker	364(65.5)	192(34.5)		220(60.4)	144(39.6)		196(89.1)	24(10.9)	
Clinical Stage									
T1	293(65.7)	153(34.3)	.732	176(60.1)	117(39.9)	.340	158(89.8)	18(10.2)	.199
T2	93(64.1)	52(35.9)		61(65.6)	32(34.4)		51(83.6)	10(16.4)	
Pathology Stage									
T2	293(65.4)	155(34.6)	.978	181(61.8)	112(38.2)	.703	158(87.3)	23(12.7)	.444
T3	94(65.3)	50(34.7)		56(59.6)	38(40.4)		51(91.1)	5(8.9)	
Gleason Score									
Well (2-4)	13(48.2)	14(51.9)		8(61.5)	5(38.5)		6(75.0)	2(25.0)	
Moderately (5-6)	282(66.8)	140(33.2)	.228	170(60.3)	112(39.7)	.476	150(88.2)	20(11.8)	.177
Moderately Poorly (7)	79(64.8)	43(35.3)		53(67.1)	26(32.9)		49(92.5)	4(7.6)	
Poorly (8-10)	13(59.1)	9(40.9)		6(46.2)	7(53.9)		4(66.7)	2(33.3)	
In-house Surgery									
Yes	323(67.3)	157(32.7)	.060	196(60.7)	127(39.3)	.675	178(90.8)	18(9.2)	.005
No	63(57.8)	46(42.2)		40(63.5)	23(36.5)		30(75.0)	10(25.0)	

*Numbers may not add up to totals due to missing information
Percentages may not add up to 100 due to rounding.

Table 2 . Demographic characteristics for patients who underwent a radical prostatectomy, stratified by level of dysfunction at time of interview (n=209)

Numbers (percentages)*	Both Sexual and Urinary Dysfunction n=40	Sexual Dysfunction Only n=95	Neither Dysfunction n=74	Chi-Sq p value
Race				
African American/Other	4 (20)	7(35)	9(45)	.573
White	36 (19)	88(47)	65(34)	
Marital Status				
Married	34(18)	87(47)	65(35)	.311
Never Married	3(43)	3(43)	1(14)	
Wid/Div/Sep	3(19)	5(31)	8(50)	
Education				
<high school	2(33)	3(50)	1(17)	
high school	12(27)	19(42)	14(31)	.162
some college	15(26)	26(46)	16(28)	
college	2(5)	18(47)	18(47)	
postgrad	9(15)	28(45)	25(40)	
Employment				
Retired	26(21)	54(44)	42(34)	.660
Working	14(16)	40(47)	32(37)	
Income				
<20,001	3(27)	4(36)	4(36)	
20,001 to 30,000	7(27)	15(58)	4(15)	.366
30,001 to 50,000	13(21)	26(43)	22(36)	
>50,000	15(17)	38(42)	37(41)	
Comorbidities				
0	17(16)	46(43)	44(41)	.013
1	10(15)	34(51)	23(34)	
2+	13(39)	14(42)	6(18)	
Pre-opp PSA				
<4	15(18)	46(56)	21(26)	.029
>=4	25(20)	49(39)	53(42)	
Smoking Status				
Smoker	3(30)	3(30)	4(40)	.548
Non-smoker	37(18)	90(46)	69(35)	
Clinical Stage				
T1	30(19)	75(47)	53(34)	.543
T2	10(20)	20(39)	21(41)	
Pathology Stage				
T2	30(19)	72(46)	56(35)	.995
T3	10(20)	23(45)	18(35)	
Gleason Score				
Well (2-4)	1(17)	2(33)	3(50)	
Moderately (5-6)	31(21)	67(45)	52(35)	.939
Moderately Poorly (7)	7(14)	24(49)	18(37)	
Poorly (8-10)	1(25)	2(50)	1(25)	
In-house Surgery				
Yes	34(19)	79(44)	65(37)	.780
No	6(20)	15(50)	9(30)	

*Numbers may not add up to totals due to missing information
Percentages may not add up to 100 due to rounding.

Table 3: Kruskal-Wallis Analyses and Wilcoxon Post-Hoc Comparisons of Outcome group, Race, and Comorbidity by Utility

	TTO				SG			
	N	Mean	SD	p value	N	Mean	SD	p value
Level of Dysfunction								
Both Sexual and Urinary	40	.767[a]	.310	.0007	40	.822[c,d]	.272	<.0001
Sexual Only	95	.869[b]	.209		95	.898[c,e]	.199	
Neither	74	.923[a,b]	.205		74	.956[d,e]	.165	
Race								
African American/Other	20	.841	.312	.6065	20	.955	.078	.1322
White	189	.871	.227		189	.899	.218	
Comorbidities								
0	107	.863	.252		107	.903	.218	.322
1	67	.894	.208	.352	67	.913	.215	
2+	33	.843	.227		33	.901	.155	

a Both versus Neither, TTO ; p=.015
b Sexual versus Neither, TTO; p=.0002
c Both versus Sexual, SG; p=.048
d Both versus Neither, SG; p<.0001
e Sexual versus Neither, SG; p<.0001